

Petitioner Earleen Bean-Sasser was born in 1958. Her family medical history shows that she had an uncle who suffered from rheumatoid arthritis (hereafter “RA”). Ex. 3 at 69. Additionally, her personal medical history indicates that she had at least a decade-long history of smoking one pack per day of cigarettes. *E.g.*, Ex. 13 at 259, Ex. 17 at 275, Ex. 21 at 997. Ms. Bean-Sasser was also diagnosed with carpal-tunnel syndrome in 2004. Ex. 3 at 68.

In April 2010, Ms. Bean-Sasser was exposed to a patient’s blood while tending to him as his nurse. In accordance with guidelines from the Centers for Disease Control, she received a booster dose of the hepatitis B vaccine on May 11, 2010. Pet. at 2-6, Ex. 6 at 146. Approximately 11 hours post-vaccination, Ms. Bean-Sasser began experiencing pain in her left wrist. *Jt. Stip. of Onset* at 1. After a trip to an emergency room on May 11, 2010, various tests, and a follow-up visit with her primary care provider on June 4, 2010, Ms. Bean-Sasser was ultimately diagnosed with RA. Ex. 2 at 21-40, Ex. 8 at 2813. Among the tests she received was one showing that she was positive for the rheumatoid factor (hereafter “RF”) antibody. Ex. 2 at 27.

Thereafter, Ms. Bean-Sasser sought treatment from several doctors. Through a workers’ compensation program, she saw Dr. Robert Blau, who concluded that Ms. Bean-Sasser’s RA was related to her hepatitis B booster vaccine. Ex. 3 at 79-80. Dr. Blau’s conclusion followed from certain medical literature linking the hepatitis B vaccine to arthritis, as well as from markers indicating Ms. Bean-Sasser’s genetic susceptibility. *Id.*

On September 29, 2010, she saw Dr. Paul Utz, a Stanford University rheumatologist, who concluded following a physical examination and review of her medical history that Ms. Bean-Sasser’s antibodies existed prior to her vaccination for hepatitis B. Ex. 4. Dr. Utz suggested that the vaccine could have triggered the onset of RA when it was only in a presymptomatic phase, but that it would be unlikely for the vaccine to have caused the disease outright. *Id.* at 133. Ms. Bean-Sasser also saw a second rheumatologist, Dr. William Reeder, on January 21, 2011, who noted the relationship between RA and environmental stimuli, potentially including the hepatitis B vaccine. Ex. 18 at 377-79. Ms. Bean-Sasser has continued treatment under Dr. Reeder and other physicians since 2011.

On May 9, 2013, Ms. Bean-Sasser filed a petition for compensation under the Vaccine Act, alleging that she suffered RA as a result of the hepatitis B vaccine she received in May 2010. On April 5, 2016, Special Master Moran issued his decision, *Bean-Sasser v. Sec’y of Health & Human Servs.*, No. 13-326V (Fed. Cl. Sp. Mstr. Apr. 5, 2016), denying her claim. Ms. Bean-Sasser filed a motion for review of that decision on April 28, 2016. ECF No. 76. The respondent filed its response on May 31, 2016. ECF No. 78.

LEGAL STANDARDS

This court has jurisdiction to review a special master’s decision in a Vaccine Act case upon a properly-filed petition for review. 42 U.S.C. § 300aa—12(e)(1). The court may

set aside any of the Special Master's findings of fact or conclusions of law if those determinations were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." *Id.* at 12(e)(2)(B).

The court applies different standards to conclusions of law, findings of fact, and discretionary rulings. *Masias v. Sec'y of Health & Human Servs.*, 634 F.3d 1283, 1287-88 (Fed. Cir. 2011)²; *see also Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 871 no. 10 (Fed. Cir. 1992); *Pafford v. Sec'y of Health and Human Servs.*, 64 Fed. Cl. 19, 27 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). The court reviews conclusions of law under the "not in accordance with the law" standard, findings of fact under the arbitrary and capricious standard, and discretionary rulings under the "abuse of discretion" standard. *Saunders v. Sec'y of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994).

The arbitrary and capricious standard is "well understood to be the most deferential [standard] possible." *Munn*, 970 F.2d at 870. "If the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" *Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d at 1363 (quoting *Hines on Behalf of Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)). "Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims." *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1366 (Fed. Cir. 2013) (quoting *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (internal citations omitted)).

In establishing a *prima facie* case for causation-in-fact, petitioner must "show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The preponderance standard "requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before [she] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Concrete Pipe and Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal.*, 508 U.S. 602, 622 (1993)) (additional citation and internal quotation marks omitted). The Court of Appeals for the Federal Circuit has recognized that it is petitioner's burden to do the "heavy lifting" to meet the preponderance standard in causation-in-fact cases. *Althen*, 418 F.3d at 1280; *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993).

² "Under the Vaccine Act, [the Circuit] review[s] a decision of the special master under the same standard as the Court of Federal Claims." *Masias*, 634 F.3d at 1287.

Under the first prong of *Althen*, petitioner must provide a “biologically plausible” medical theory that is “reliable” and “reputable.” *See Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1375, 1380 (Fed. Cir. 2009) (“The assessment of whether a proffered theory of causation is “reputable” can involve assessment of the relevant scientific data.”); *see also Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994) (stating that a causation theory must be supported by a “sound and reliable medical or scientific explanation”).

To guide trial courts in evaluating whether expert theories are sufficiently “reliable” for admission, the Supreme Court identified four factors for trial courts to consider, including: testing; peer review and publication; known or potential error rate; and general acceptance in the scientific community. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593-94 (1993). Special masters may evaluate opinions on causation according to the standards set forth in *Daubert*. *See Terran v. Sec’y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999); *see also Moberly*, 592 F.3d at 1324 (“Although a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness.”). A trier of fact, therefore, is not required to accept an expert’s opinion simply because the expert is found qualified to opine in a medical or scientific discipline. *Bergman v. Sec’y of Health & Human Servs.*, No. 90-1252V, 1992 WL 78671, at *7 (Cl. Ct. Spec. Mstr. Mar. 31, 1992).

Under the second prong of *Althen*, petitioner must demonstrate a sequence of cause and effect between the vaccine and injury, and that sequence must pertain specifically to her case. *Moberly*, 592 F.3d at 1322. The Vaccine Rules reiterate this relevance requirement. RCFC, App. B, Vaccine Rule 8(b)(1) (requiring that evidence considered by the special masters be “relevant” and “reliable”).

Under the third prong of *Althen*, petitioner must prove there was a proximate temporal relationship between the vaccine and injury. *De Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The onset of symptoms must therefore occur “within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation in fact.” *Id.* *See also Althen*, 418 F.3d at 1281 (equating “proximate temporal relationship” with “medically-acceptable temporal relationship.”). The Federal Circuit has reiterated the importance of providing some evidence of what qualifies as a medically-acceptable time frame: “without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm.” *Pafford v. Sec’y of Health & Human Servs.* 451 F.3d 1352, 1358 (Fed. Cir. 2006). Thus, a mere showing of temporal proximity between the vaccination and injury is insufficient to meet petitioner’s burden under prong three of *Althen*. *Id.*

It is not the role of this court to “reweigh the factual evidence,” “assess whether the Special Master correctly evaluated the evidence,” or “examine the probative value of the

evidence or the credibility of the witnesses.” *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2010).

DISCUSSION

In her motion for review, Ms. Bean-Sasser raised two principal objections to the decision of Special Master Moran: (1) that he incorrectly found Ms. Bean-Sasser was suffering from rheumatoid arthritis (RA) at the time she received her hepatitis B vaccine; and (2) that he incorrectly found Ms. Bean-Sasser to have failed to satisfy Prong 1 of the test established in *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Ms. Bean-Sasser thus argues that, as a finding of fact, Special Master Moran’s conclusion that she already had RA when she received her vaccine was arbitrary and capricious; Special Master Moran’s application of Prong 1 of the test laid out in *Althen* necessarily follows from and relies upon this determination.

In his analysis, Special Master Moran considered the potential causal relationship between Ms. Bean-Sasser’s hepatitis B vaccination and the manifestation of her RA symptoms, noting a number of pertinent medical factors which are associated with increased risk of developing RA, irrespective of whether or not the subject has received the hepatitis B vaccine. These factors included her age, her gender, the incidence of RA in a second-degree relative, a history of smoking, and the presence of RF antibodies consistent with a physiological response to extant RA. Dec. at 9.

Special Master Moran also considered the testimony and reports of Drs. Charlesworth and Lightfoot, the two principal experts advanced by the respective parties. The Special Master compared the experience and relevant medical training of each expert, acknowledging that both doctors were knowledgeable and respected practitioners in their fields of specialty – Dr. Charlesworth in immunology, Dr. Lightfoot in rheumatology. *Id.* at 9-10. However, Special Master Moran noted that Dr. Charlesworth had not personally assessed a case of RA in over two decades, suggesting a comparative lack of experience with the condition, and could not point to specific studies, commonly-accepted theories about the potential relationship between RA and the hepatitis B vaccine, or other salient medical literature to buttress the argument that Ms. Bean-Sasser’s vaccination could have led to the onset of her RA. *Id.* at 10, 16-17. By contrast, Special Master Moran recognized Dr. Lightfoot as a “leading rheumatologist” with decades of specific experience treating RA. He also noted commonplace medical literature that indicated wide acceptance of, for example, the connection between the presence of RF antibodies and the incidence of RA in patients, suggesting a logical association wherein a patient with RF antibodies generally already has RA when such antibodies are detected in her system. *Id.* at 3, 9-11, 18. Special Master Moran pointed directly to Dr. Lightfoot’s experience and familiarity with RA to explain why he found the argument that Ms. Bean-Sasser’s condition was not caused by her vaccination to be the more persuasive one. *Id.* at 9.

After consideration of her pre-existing medical history as well as of the timing of her symptoms in relation to the administration of the vaccine, in concordance with his

assessment of the expert witnesses' testimony and the comparative plausibility of their respective theories, Special Master Moran determined that Ms. Bean-Sasser's RA was likely already present at the time she was vaccinated against hepatitis B. *Id.* at 11.

Ms. Bean-Sasser's objection to the factual determination of the Special Master is understandable, but ultimately unpersuasive. As stated previously, the court reviews a special master's factual conclusions under the arbitrary and capricious standard, the most deferential standard of all. *Munn*, 970 F.2d at 870. After careful review of the case record and the Special Master's decision, the court holds that the factual finding that Ms. Bean-Sasser's RA was present prior to the administration of the hepatitis B vaccine was neither arbitrary nor capricious. The decision reflects the Special Master's careful review of all the evidence presented before him and details his thought process in weighing the evidence of Ms. Bean-Sasser's medical history as well as statements from expert witnesses provided both by her and by the respondent. Special Master Moran duly considered the various factors that made the incidence of RA likely in Ms. Bean-Sasser, and weighed the testimony and qualifications of Dr. Charlesworth alongside the testimony and qualifications of Dr. Lightfoot. The court sees no reason here to doubt the evidentiary veracity of the Special Master's review of the record or his findings of fact based upon it. Because it is not the role of the court to reweigh the factual evidence itself, the court must afford the proper weight to the Special Master's findings of fact.

Special Master Moran's comparison of the two principal experts was also justified in the context of their arguments, qualifications, and the details of Ms. Bean-Sasser's RA. Special masters may consider a specialist's history or familiarity with a given disease or disorder when applying that specialist's testimony to determining when or how the disorder first manifested in a patient. *Terran*, 195 F.3d at 1316 (special masters may "determine whether the testimony has a reliable basis in the knowledge and experience of [the relevant] discipline"). While Ms. Bean-Sasser also offered the testimony of additional medical practitioners who participated in her course of treatment, including Dr. Utz and Dr. Paul Windham, these doctors' theories for the onset of her RA lent a fair amount of support to Dr. Lightfoot's argument disconnecting her RA from her hepatitis B vaccination. Dr. Utz's statement, for example, suggested that the vaccine triggered the onset of Ms. Bean-Sasser's RA, but also noted a high likelihood that her condition had already begun when the vaccine was administered. Dec. at 7, 11-12. Similarly, Dr. Windham's pre-litigation notes posited that the temporal proximity of the vaccination and the onset of RA symptoms was mere "serendipity," hardly the sort of persuasive causal opinion the Special Master would be expected to find dispositive in reaching findings of fact in this case. *Id.* at 6, 11. Assessments by special masters of the comparative credibility of witnesses or of competing medical theories are "virtually unchallengeable on appeal" and are unlikely to fail challenges alleging that they are arbitrary or capricious absent a clear and definitive demonstration thereof. *See Lampe*, 219 F.3d at 1361-62. While there may be reasonable disagreement over Special Master Moran's ultimate accord with Dr. Lightfoot that the hepatitis B vaccine was not responsible for causing Ms. Bean-Sasser to present symptoms of RA, it was not arbitrary or capricious for him to do so.

Additionally, Ms. Bean-Sasser objected to Special Master Moran's rejection of the medical theory advanced under prong one of the *Althen* test. In *Althen*, the Federal Circuit held that in order to establish entitlement to a vaccine Program award of compensation, a petitioner must satisfy three criteria: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Under the first prong of *Althen*, Ms. Bean-Sasser was required to offer a reliable medical theory explaining how her RA was caused by the hepatitis B vaccine. That theory required support from either medical records or expert opinions pertaining specifically to her case. *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992); *Moberly*, 592 F.3d at 1322. In support, Ms. Bean-Sasser argued that the Federal Circuit's decision in *Capizzano v. Sec'y of Health & Human Servs.* established the plausibility of this RA-hepatitis B vaccine causal relationship. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317 (Fed. Cir. 2006). However, the Federal Circuit has also recognized that "[a] special master's acceptance of a theory in one case does not require him or her to accept the theory in a subsequent case involving similar facts or the same vaccine. Rather, a different evidentiary record can lead to different outcomes." *Bast v. Sec'y of Health & Human Servs.*, 117 Fed. Cl. 104, 124 (2014); *Moberly*, 592 F.3d at 1325 ("Because the evidentiary record in the *Andreu* case is significantly different from the record in this case, the result in *Andreu* does not compel the same result here"). As medicine and science continue to advance, so does our understanding about the causes of diseases and the causal relationship between vaccines and side events. When the evidence presented differs, a different result is also plausible. *Id.* (quoting *Lehner v. Sec'y of Health & Human Servs.*, No. 08-554V, 2015 WL 5443461, at *40 (Fed. Cl. Spec. Mstr. July 22, 2015)).

While Ms. Bean-Sasser questioned Dr. Lightfoot's reliability given his apparent unfamiliarity with the facts and outcome in *Capizzano*, that criticism is broadly irrelevant to the question of whether his theory here is believable. Dr. Lightfoot was not proffered as an expert in *Capizzano*, a case with different facts and a different proposed mechanism of injury. Dr. Lightfoot's medical background and expertise in treating RA were the purpose for and persuasive force behind his arguments, and the bases upon which the special master assessed his theories about whether the hepatitis B vaccine was more likely than not to have caused Ms. Bean-Sasser's RA. Medical background and expertise were also the bases upon which the Special Master assessed Dr. Charlesworth's theories. Dec. at 9-12. Dr. Lightfoot's statements and personal expertise on the subject of rheumatology speak for themselves, and whether or not the doctor was familiar with another case has little bearing on the ultimate strength of his assertions in this case that he did not believe there was a causal link between the vaccine and Ms. Bean-Sasser's RA.

Furthermore, this case presents clear factual distinctions from *Capizzano*, particularly with respect to evidence presented. A study critical to the conclusion in *Capizzano* was not filed by Ms. Bean-Sasser in this case, and a more recent epidemiological study published several years after the *Capizzano* decision was included

in the body of evidence she presented – a study which failed to indicate any association between exposure to the hepatitis B vaccine and RA. Dec. at 15,18. Special Master Moran noted that this indicated an evolution in the understanding of RA over time, and that it supported his ultimate conclusion not to accept the Federal Circuit’s fact-specific finding in *Capizzano* regarding RA and the hepatitis B vaccine. *Id.*

Special masters are entitled to expect that experts’ assertions be supported by indicators of their reliability. *See Moberly*, 592 F.3d at 1324. The Special Master thoroughly evaluated the theory proffered by Dr. Charlesworth, but found that it was not persuasive and lacked medical support as it related to the specific facts of this case, particularly in contrast to Dr. Lightfoot’s support and argument for the theory that there was not a connection between the vaccine and Ms. Bean-Sasser’s RA. Given these determinations and their sound logical and defensible nature, Special Master Moran’s determination that Ms. Bean-Sasser did not establish the first prong of *Althen* was not in error.

Overall, the Special Master’s assessment of the experts, medical records, and other evidence and conclusion that Ms. Bean-Sasser had failed to demonstrate a causal link between her hepatitis B vaccine and her RA was not arbitrary or capricious. The record reflects that the Special Master carefully and thoroughly weighed the evidence before him and determined that Ms. Bean-Sasser had not provided a legally-probable theory of causation-in-fact. Special Master Moran appropriately evaluated the parties’ expert witnesses’ credibility, considering their professional credentials, familiarity with the specifics of Ms. Bean-Sasser’s condition, and ability to articulate persuasive, supportable theories.

Ms. Bean-Sasser now asks the court to reconsider the Special Master’s determinations, a reconsideration the court views as unnecessary and duplicative of effort in light of the quality of the initial review by Special Master Moran. While she may disagree with his conclusions, there is nothing in them to suggest that either his finding that Ms. Bean-Sasser was likely to have RA prior to her hepatitis B vaccination, or his rejection of her theory that the vaccine caused her RA, was arbitrary or capricious. The record shows, and the Special Master’s decision bears out, that he carefully and thoroughly weighed the evidence, medical history, studies, expert testimony, and legal arguments of both parties before arriving at his final determinations.

CONCLUSION

Accordingly, petitioner’s MOTION for review is DENIED. The Special Master’s decision is affirmed. The Clerk is hereby directed to enter judgment according to the Special Master’s decision. **IT IS SO ORDERED.**

s/Robert J. Yock

Robert J. Yock
Senior Judge